TITLE 180 CONTROL OF RADIATION

CHAPTER 6 X-RAYS IN THE HEALING ARTS

APPENDIXES

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TITLE 180 CONTROL OF RADIATION

CHAPTER 6 X-RAYS IN THE HEALING ARTS

6-001 SCOPE AND AUTHORITY

6-001.01 180 NAC 6 establishes requirements, for which a registrant is responsible, for use of x-ray equipment by or under the supervision of an individual authorized by and licensed in accordance with state statutes to engage in the healing arts or veterinary medicine. The regulations are authorized by and implement the Nebraska Radiation Control Act, Neb. Stat. Rev. sections 71-3501 to 3519.

6-001.02 The use of x-ray equipment for the intentional exposure of individuals for diagnosis or treatment shall be by or under the supervision of one licensed to practice the healing arts in Nebraska.

6-001.03 The use of x-ray equipment in the practice of veterinary medicine shall be by or under the supervision of an individual authorized to practice veterinary medicine in the State of Nebraska.

6-001.04 The provisions of 180 NAC 6 are in addition to, and not in substitution for, other applicable provisions of 180 NAC 1, 2, 4, 9, 10, 15, 16, 17 and 18.

6-002 DEFINITIONS: As used in Title 180, the following definitions apply:

Accessible surface means the external surface of the enclosure or housing provided by the manufacturer.

Added filtration means any filtration which is in addition to the inherent filtration.

Aluminum equivalent means the thickness of type 1100 aluminum alloy[1] affording the same attenuation, under specified conditions, as the material in question.

Assembler means any person assembling, replacing, or installing one or more components into an x-ray system or subsystem. It includes adjustment of components which affect output of radiation

[1]The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, maximum 0.12 percent copper.

generating equipment. The term includes the owner of an x-ray system or his employee or agent who assembles components into an x-ray system that is subsequently used to provide professional or commercial services.

Attenuation block means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy[2] or other materials having equivalent attenuation.

Automatic exposure control means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation (See also"Phototimer")

Barrier (See “Protective barrier”).

Beam axis means a line from the source through the centers of the x-ray fields.

Beam-limiting device means a device that provides a means to restrict the dimensions of the x-ray field.

Beam monitoring system means a system designed to detect and measure the radiation present in the useful beam.

Cephalometric device means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

Certified components means components of x-ray systems which are subject to regulations promulgated under Public Law 90-602, the Radiation Control for Health and Safety Act of 1968 because they come within the definitions in Section 355 (1) and (2) of that law, attached hereto as Attachment Number 6-1 and incorporated herein by this reference.

Certified system means any x-ray system which has one or more certified component(s).

Changeable filters means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical or physical process.

Coefficient of variation or "C" means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{s}{\bar{x}} = \frac{1}{\bar{x}}\left[\frac{\sum_{i=1}^{n}\left(x_1 - \bar{x}\right)^2}{n-1}\right]^{1/2}$$

where

s = Estimated standard deviation of the population.

[2]Ibid.

X = Mean value of observations in sample.
X_i = i^{th} observation in sample.
n = Number of observations in sample.

Computed tomography means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

Contact therapy system means an x-ray system used for therapy with the x-ray tube port placed in contact with or within 5 centimeters of the surface being treated.

Control panel means that part of the x-ray control upon which are mounted the switches, knobs, push-buttons, and other hardware necessary for manually setting the technique factors.
Cooling curve means the graphical relationship between heat units stored and cooling time.
"CT" (See "Computed tomography").

Deadman switch means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

Detector (See Radiation detector).

Diagnostic source assembly means the tube housing assembly with a beam-limiting device attached.

Diagnostic x-ray system means an x-ray system designed for irradiation of any part of the human body for the purpose of diagnosis or visualization.

Direct scattered radiation means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam (See "Scattered radiation").

Entrance exposure rate means the exposure per unit time at the point where the center of the useful beam enters the patient.

Equipment (See "X-ray equipment").

Field emission equipment means equipment which uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

Filter means material placed in the useful beam to absorb preferentially selected radiations.

Fluoroscopic imaging assembly means a subsystem in which x-ray photons produce a fluoroscopic image. It includes the image receptor(s) such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

Focal spot means the area projected on the anode of the x-ray tube by the electrons accelerated from the cathode and from which the useful beam originates.

General purpose radiographic x-ray system means any radiographic x-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.

Gonad shield means a protective barrier for the testes or ovaries.

Half-value layer means the thickness of specified material which attenuates the beam of radiation to an extent such that the exposure rate is reduced to one-half of its original value. In this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

Healing arts screening means the testing of human beings using x-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment.

Heat unit means a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds, i.e., kVp x mA x second.

HVL (See "Half-value layer").

Image intensifier means a device, installed in its housing, which instantaneously converts an x-ray pattern into a corresponding light image of higher energy density.

Image receptor means any device, such as a fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations.

Image receptor support means, for mammographic systems, that part of the system designed to support the image receptor in a horizontal plane during a mammographic examination.

Inherent filtration means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

Irradiation means the exposure of matter to ionizing radiation.

Kilovolts peak (See "Peak tube potential").

kV means kilovolts.

kVp (See Peak tube potential).

kWs means kilowatt second. It is equivalent to E + 3 kV mA s, i.e.,

$$(A)kWs = (X)kV \times (Y)mA \times (Z)s \times \frac{kWs}{E+3\ kV \times mA \times s} = \frac{XYZ\ kWs}{E+3}$$

Lead equivalent means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

Leakage radiation means radiation emanating from the diagnostic or therapeutic source assembly except for the useful beam.

Leakage technique factors means the technique factors associated with the diagnostic or therapeutic source assembly which are used in measuring leakage radiation. They are defined as follows:

1. For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs, i.e., 10 milliampere seconds, or the minimum obtainable from the unit, whichever is larger.

2. For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential.

3. For all other diagnostic or therapeutic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

Light field means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.

Line-voltage regulation means the difference between the no-load and the load line potentials expressed as a percent of the load line potential. It is calculated using the following equation:

Percent line-voltage regulation = 100 $(V_n-V_1)/V_1$ where
V_n = No-load line potential and
V_1 = Load line potential

Linear attenuation coefficient or u means the quotient of dN/N divided by d1 when dN/N is the fraction of unchanged ionizing radiation that experience interactions in traversing a distance d1 in a specified material.

uC/kg means microcoulomb/kilogram.

mA means milliampere.

mAs means milliampere second.

mC/kg means millicoulomb/kilogram.

Maximum line current means the root-mean-square current in the supply line of an x-ray machine operating at its maximum rating.

Mobile x-ray equipment (See X-ray equipment).

nC/kg means nanocoulomb/kilogram.

Patient means an individual subjected to healing arts examination, diagnosis, or treatment.

Peak tube potential means the maximum value of the potential difference across the x-ray tube during an exposure.

Phantom means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation.

Phototimer means a method for controlling radiation exposures to image receptors by the amount of radiation which reaches a radiation monitoring device(s). The radiation monitoring device(s) is part of an electronic circuit which controls the duration of time the tube is activated (See "Automatic exposure control").

PID (See "Position indicating device").

Portable x-ray equipment (See X-ray equipment).

Position indicating device means a device on dental x-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.

Primary dose monitoring system means a system which will monitor the useful beam during irradiation and which will terminate irradiation when a pre-selected number of dose monitor units have been acquired.

Primary protective barrier (See Protective barrier).

Protective apron means an apron made of radiation absorbing materials used to reduce radiation exposure.

Protective barrier means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

Primary protective barrier means the material, excluding filters, placed in the useful beam, for protection purposes, to reduce the radiation exposure.

Secondary protective barrier means a barrier sufficient to attenuate the stray radiation to the required degree.

Protective glove means a glove made of radiation absorbing materials used to reduce radiation exposure.

Qualified expert with reference to radiation protection, a person having the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs (for example, persons certified in this field by the American Board of Radiology, or the American Board of Health Physics, or those having equivalent qualifications). With reference to the calibration of radiation therapy equipment, a person having in addition to the above qualifications, training and experience in the clinical applications of radiation physics to radiation therapy (for example, persons certified in Radiological Physics or X-ray and Radium Physics by the American Board of Radiology, or those having equivalent qualifications) or meets the minimum qualifications specified in 180 NAC 15-013.03.

Radiation detector means a device which in the presence of radiation provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

Radiation therapy simulation system means a fluoroscopic or radiographic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

Radiograph means an image receptor on which the image is created directly or indirectly by an x-ray pattern and results in a permanent record.

Radiographic imaging system means any system whereby a permanent or semi-permanent image is recorded on an image receptor by the action of ionizing radiation.

Radiological physicist means an individual who meets the requirements of 180 NAC 15-013.01 Radiological Medical Physicist or 180 NAC 15-013.02 Radiological Health Physicist.

Rating means the operating limits as specified by the component manufacturer.

Recording means producing a permanent form of an image resulting from x-ray photons.

Response time means the time required for an instrument system to reach 90 percent of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady state midscale reading.

Scattered radiation means radiation that, during passage through matter, has been deviated in direction (See "Direct scattered radiation").

Secondary dose monitoring system means a system which will terminate irradiation in the event of failure of the primary system.

Secondary protective barrier (See "Protective barrier").

Shutter means a device attached to the tube housing assembly which can totally intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

SID (See Source-image receptor distance).

Source means the focal spot of the x-ray tube.

Source-image receptor distance means the distance from the source to the center of the input surface of the image receptor.

Special purpose x-Ray system means any radiographic x-ray system which, by design, is limited to radiographic examination of a specific anatomical region.

Spot check means a procedure which is performed to assure that a previous calibration continues to be valid.

Spot film means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

Spot-film device means a device intended to transport and/or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.

SSD means the distance between the source and the skin of the patient.

Stationary x-ray equipment (See X-ray equipment).

Stray radiation means the sum of leakage and scattered radiation.

Technique factors means the conditions of operation. They are specified as follows:

1. For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;

2. For field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses;

3. For CT x-ray systems designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in mA, x-ray pulse width in seconds, and the number of x-ray pulses per scan, or the product of tube current, x-ray pulse width, and the number of x-ray pulses in mAs;

4. For CT x-ray systems not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; and

5 For all other equipment, peak tube potential in kV and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

Termination of irradiation means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

Tomogram means the depiction of the x-ray attenuation properties of a section through the body.

Traceable to a national standard means that a quantity or a measurement has been compared to a national standard directly or indirectly through one or more intermediate steps and that all comparisons have been documented.

Tube means an x-ray tube, unless otherwise specified.

Tube housing assembly means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.

Tube rating chart means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

Useful beam means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam-limiting device when the exposure controls are in a mode to cause the system to produce radiation.

Variable-aperture beam-limiting device means a beam-limiting device which has capacity for stepless adjustment of the x-ray field size at a given SID.

Visible area means that portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.

Wedge filter means an added filter effecting continuous progressive attenuation on all or part of the useful beam.

X-ray control means a device which controls input power to the x-ray high-voltage generator and/or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices, which control the technique factors of an x-ray exposure.

X-ray equipment means an x-ray system, subsystem, or component thereof. Types of x-ray equipment are as follows:

Mobile x-ray equipment means x-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled.

Portable x-ray equipment means x-ray equipment designed to be hand-carried.

Stationary x-ray equipment means x-ray equipment which is installed in a fixed location.

X-ray field means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.

X-ray high-voltage generator means a device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high-voltage switches, electrical protective devices, and other appropriate elements.

X-ray system means an assemblage of components for the controlled production of x-rays, including, but not limited to, an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system shall be considered integral parts of the system.

X-ray subsystem means any combination of two or more components of an x-ray system.

X-ray tube means any electron tube which is designed to be used primarily for the production of x-rays.

6-003 GENERAL REQUIREMENTS

6-003.01 Administrative Controls

1. Registrant: The registrant shall be responsible for directing the operation of the x-ray system(s) under his administrative control. The registrant or the registrant's agent shall assure that the requirements of 180 NAC 6-003.01, item 1. are met in the operation of the x-ray system(s).

   a. An x-ray system which does not meet the provisions of Title 180 shall not be operated for diagnostic or therapeutic purposes, unless the Agency makes a finding that its continued use will not constitute a risk to the health and safety of the public.
   b. Registrants shall assure that individuals who will operate x-ray systems under the direction of healing arts practitioners shall meet the requirements as specified in 180 NAC 16. The Limited X-Ray System Operator shall be instructed in the radiation safety and use of the x-ray equipment as specified in 180 NAC 16-005.
   c. A chart shall be provided in the vicinity of the diagnostic x-ray system's control panel which specifies, for all examinations performed with that system, the following information.

      (1) Patient's anatomical size versus technique factors to be utilized;
      (2) Type and focal distance of the grid to be used, if any;
      (3) Source to image receptor distance to be used;
      (4) Type and location of placement of gonad shielding to be used; and
      (5) Type and size of the film or film-screen combination to be used.

   d. Written safety procedures shall be provided to each individual operating x-ray equipment, including any restrictions of the operating technique required for the safe operation of the particular x-ray system. The operator shall be able to demonstrate familiarity with these procedures.

      (1) Doors that are an integral part of room shielding shall be closed during x-ray procedures; and
      (2) The door in 180 NAC 6-003.01, item 1.d.(1). shall be posted "Close door during x-ray procedures".

   e. Except for patients who cannot be moved out of the room, only the staff and ancillary personnel required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:

      (1) All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by 0.5 millimeter lead equivalent.
      (2) Staff and ancillary personnel shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent.
      (3) Patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of 0.25 millimeter lead equivalent or shall be so positioned that the nearest portion of the body is at least 2 meters from both the tube head and the nearest edge of the image receptor.

f. Gonad shielding of not less than 0.25 millimeter lead equivalent shall be used for patients, who have not passed the reproductive age, during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.

g. Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:

(1) Exposure of an individual for training, demonstration, or other non-healing-arts purposes; and
(2) Exposure of an individual for the purpose of healing arts screening except as authorized by 180 NAC 6-003.01,I item 1.k.

h. When a patient or film must be provided with auxiliary support during a radiation exposure:

(1) Mechanical holding devices shall be used when the technique permits. The written safety procedures, required by 180 NAC 6-003.01, item 1., d., shall list projections where holding devices cannot be utilized;
(2) The human holder shall be protected as required by 180 NAC 6-003, item 1.e.;
(3) No individual shall be used routinely to hold film or patients;
(4) Written safety procedures, as required by 180 NAC 6-003.01 ,item 1.d.; shall indicate the requirements for selecting a holder and the procedure the holder shall follow; and

(5) In those cases where the patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material.

i. Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.

(1) The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objective of the examinations.
(2) The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.
(3) Portable or mobile x-ray equipment shall be used only for examinations where it is impractical to transfer the patient(s) to a stationary x-ray installation.
(4) X-ray systems subject to 180 NAC 6-006 shall not be utilized in procedures where the source to patient distance is less than 30 centimeters.

j. All individuals who are associated with the operation of an x-ray system are subject to the requirements of 180 NAC 4-005, 4-050 and 4-022. In addition:

(1) When protective clothing or devices are worn on portions of the body and a personnel monitoring device(s) is required, at least one such monitoring device shall be utilized as follows:

(a) When an apron is worn, the monitoring device shall be worn at the collar outside the apron.
(b) The dose to the whole body based on the maximum dose attributed to the most critical organ shall be recorded in the reports required by 180 NAC 4-052. If more than one device is used and a record is made of the data, each dose shall be identified with the area where the device was worn on the body.

(2) Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.

k. Healing Arts Screening: Any person proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the Agency. When requesting such approval, that person shall submit the information outlined in Appendix A of 180 NAC 6. If any information submitted to the Agency becomes invalid or outdated, the Agency shall be immediately notified.

2. Information and Maintenance Record and Associated Information: The registrant shall maintain the following information for each x-ray system for inspection by the Agency:

   a. Model and serial numbers of all certifiable components;
   b. Aluminum equivalent filtration of the useful beam, including any routine variation;
   c. Records of surveys, calibrations, maintenance, and modifications performed on the x-ray system(s) after June 27, 1983 with the names of persons who performed such services.
   d. A scale drawing shall be available of the room in which a stationary x-ray system is located with such drawing indicating the use of areas adjacent to the room and an estimation of the extent of occupancy by an individual in such areas. In addition, the drawing shall include:

      (1) The results of a survey for radiation levels present at the operator's position and at pertinent points outside the room at specified test conditions; or
      (2) The type and thickness of materials, or lead equivalency, of each protective barrier; and

   e. A copy of all correspondence with this Agency regarding that x-ray system.

6-003.02 X-Ray Log: Each facility shall maintain an x-ray log or chart containing the patient's name, the type of examinations, and the dates the examinations were performed. When the patient or film must be provided with human auxiliary support, the name of the human holder shall be recorded.

6-003.03 Plan Review

1. Prior to construction, the floor plans and equipment arrangement of all new installations, or modifications of existing installations, utilizing x-rays for diagnostic or therapeutic purposes shall be submitted to a qualified expert or the Agency for review and comment. The required information is denoted in Appendices 2 and 3 of 180 NAC 6.
2. The Agency may require the applicant to utilize the services of a qualified expert to determine the shielding requirements prior to the plan review and comment. For particle accelerator facilities the qualified expert shall be a radiological physicist.
3 The review of such plans shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in 180 NAC 4-005, 4-011 and 4-013.

6-004 GENERAL REQUIREMENTS FOR ALL DIAGNOSTIC X-RAY SYSTEMS: In addition to other requirements of 180 NAC 6-004 all diagnostic x-ray systems shall meet the following requirements:

6-004.01 Warning Label: The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This x-ray unit may be

dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

6-004.02 Battery Charge Indicator: On battery-powered x-ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

6-004.03 Leakage Radiation from the Diagnostic Source Assembly: The leakage radiation from the diagnostic source assembly measured at a distance of l meter in any direction from the source shall not exceed 100 milliroentgens (25.8 uC/kg) in 1 hour when the x-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

6-004.04 Radiation from Components Other Than the Diagnostic Source Assembly: The radiation emitted by a component other than the diagnostic source assembly shall not exceed 2 milliroentgens (0.516 uC/kg) in 1 hour at 5 centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

6-004.05 Beam Quality

1. Half-value Layer

   a. The half-value layer of the useful beam for a given x-ray tube potential shall not be less than the values shown in Table I. If it is necessary to determine such half-value layer at an x-ray tube potential which is not listed in Table I, linear interpolation or extrapolation may be made.

TABLE I

Design operating range (kVp)	Measured Potential (kVp)	Half-value layer (mm of aluminum)
Below 51	30	0.3
	40	0.4
	50	0.5
51 to 70	51	1.2
	60	1.3
	70	1.5
Above 70	71	2.1
	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2
	130	3.5
	140	3.8
	150	4.1

b. The requirements of 180 NAC 6-004.05, item 1.a. will be considered to have been met if it can be demonstrated that the aluminum equivalent of the total filtration in the primary beam is not less than that shown in Table II.

TABLE II

Filtration Required vs. Operating Voltage

Operating Voltage (kVp)	Total Filtration (inherent plus added) (millimeters aluminum equivalent)
Below 50	0.5 millimeters
50 - 70	1.5 millimeters
Above 70	2.5 millimeters

c. In addition to the requirements of 180 NAC 6-004.05, item 1.a. all intraoral dental radiographic systems manufactured on and after December 1, 1980, shall have a minimum half-value layer not less than 1.5 millimeter aluminum equivalent filtration permanently installed in the useful beam.

d. Beryllium window tubes shall have a minimum of 0.5 millimeter aluminum equivalent filtration permanently installed in the useful beam.

e. For capacitor energy storage equipment, compliance with the requirements of 180 NAC 6-004.05 shall be determined with the maximum quantity of charge per exposure.

f. The required minimal aluminum equivalent filtration shall include the filtration contributed by all materials which are always present between the source and the patient.

2. Filtration Controls: For x-ray systems which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter(s) and shall prevent an exposure unless the minimum amount of filtration required by 180 NAC 6-004.05, item 1.a. is in the useful beam for the given kVp which has been selected.

6-004.06 Multiple Tubes: Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the x-ray control panel and at or near the tube housing assembly which has been selected.

6-004.07 Mechanical Support of Tube Head: The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during the exposure unless the tube housing movement is a designed function of the x-ray system.

6-004.08 Technique Indicators

1. The technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated.
2. The requirement of 180 NAC 6-004.08, item 1. may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

6-004.09 Structural Shielding: Structural shielding shall be provided as necessary to meet the requirements of 180 NAC 4-005, 4-022, and 4-013.

6-005 FLUOROSCOPIC X-RAY SYSTEMS: All fluoroscopic x-ray systems shall meet the following requirements:

6-005.01 Limitation of Useful Beam

1. Primary Barrier

   a. The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross-section of the useful beam at any SID.
   b The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the entire useful beam.

2. X-Ray Field

   a. Use of nonimage-intensified fluoroscopic equipment shall not be used.
   b. For image-intensified fluoroscopic equipment, neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID. In addition:

      (1) Means shall be provided to permit further limitation of the field. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID and/or a visible area of greater than 300 square centimeters shall be provided with means for stepless adjustment of the x-ray field;
      (2) All equipment with a fixed SID and a visible area of 300 square centimeters or less shall be provided with either stepless adjustment of the x-ray field or with means to further limit the x-ray field size at the plane of the image receptor to 125 square centimeters or less. Stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size of 5 by 5 centimeters or less;
      (3) For equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor; and
      (4) Compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor. For rectangular x-ray

fields used with circular image receptor, the error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.

c. Spot-film devices which are certified components shall meet the following additional requirements, except when the spot-film device is provided for use with a radiation therapy simulation system:

(1) Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot-film selector. Such adjustment shall be automatically accomplished when the x-ray field size in the plane of the film is greater than that of the selected portion of the film. If the x-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option;

(2) It shall be possible to adjust the x-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID shall be equal to, or less than, 5 centimeters by 5 centimeters;

(3) The center of the x-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within 2 percent of the SID; and

(4) On spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

6-005.02 Activation of the Fluoroscopic Tube: X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

6-005.03 Exposure Rate Limits

1. Entrance Exposure Rate Allowable Limits

a. The exposure rate measured at the point where the center of the useful beam enters the patient shall not exceed 10 roentgens (2.58 mC/kg) per minute, except during recording of fluoroscopic images or when provided with optional high level control.

b When provided with optional high level control, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens (1.29 mC/kg) per minute at the point where the center of the useful beam enters the patient unless the high level control is activated.

(1) Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator.
(2) A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

c. In addition to the other requirements of 180 NAC 6-005, certified systems which do not incorporate an automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens (1.29 mC/kg) per minute at the point where the center of beam enters the patient except during recording of fluoroscopic images or when provided with an optional high level control.

d. Compliance with the requirements of 180 NAC 6-005.03 shall be determined as follows:

(1) Movable grids and compression devices shall be removed from the useful beam during the measurement.
(2) If the source is below the table, exposure rate shall be measured 1 centimeter above the tabletop or cradle.
(3) If the source is above the table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.
(4) In a C-arm type of fluoroscope, the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly.

e. Periodic measurement of entrance exposure rate shall be performed as follows:

(1) Such measurements shall be made annually or after any maintenance of the system which might affect the exposure rate.
(2) Results of these measurements shall be posted where any fluoroscopist may have ready access to such results while using the fluoroscope and in the record required in 180 NAC 6-003.01, item 2., c. The measurement results shall be stated in roentgens (C/kg) per minute and include the technique factors used in determining such results. The name of the person performing the measurements and the date the measurements were performed shall be included in the results.
(3) Personnel monitoring devices may be used to perform the measurements required by 180 NAC 6-005.03, item 1.e.(1), provided the measurements are made as described in 180 NAC 6-005.03, item 1, e.(4).
(4) Conditions of periodic measurement of entrance exposure rate are as follows:

(a) The measurement shall be made under the conditions that satisfy the requirements of 180 NAC 6-005.03, item 1.d.
(b) The kVp shall be the kVp typical of clinical use of the x-ray system;

(c) The x-ray system(s) that incorporates automatic exposure control shall have sufficient material placed in the useful beam to produce a milliamperage typical of the use of the x-ray system; and

(d) X-ray system(s) that do not incorporate an automatic exposure control shall utilize a milliamperage typical of the clinical use of the x-ray system. Materials should be placed in the useful beam when conducting these periodic measurements to protect the imaging system.[3]

6-005.04 Barrier Transmitted Radiation Rate Limits

1. The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed 2 milliroentgens (0.516 uC/kg) per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.
2. Measuring Compliance of Barrier Transmission

    a. The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.
    b. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop.
    c. If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters.
    d. Movable grids and compression devices shall be removed from the useful beam during the measurement.
    e. The attenuation block shall be positioned in the useful beam 10 centimeters from the point of measurement of entrance exposure rate and between this point and the input surface of the fluoroscopic imaging assembly. Closer distances may be used if corrections are applied for poor geometry.

6-005.05 Indication of Potential and Current: During fluoroscopy and cinefluorography, the kV and the mA shall be continuously indicated.

6-005.06 Source-to-Skin Distance: The SSD shall not be less than:

1. 38 centimeters on stationary fluoroscopes installed after June 27, 1983,
2. 35.5 centimeters on stationary fluoroscopes which were in operation prior to November 23, 1990.
3. 30 centimeters on all mobile fluoroscopes, and

[3]Materials should be placed in the useful beam when conducting these periodic measurements to protect the imaging system.

4. 20 centimeters for image intensified fluoroscopes used for specific surgical application. The written safety procedures must provide precautionary measures to be adhered to during the use of this device.

6-005.07. Fluoroscopic Timer

1. Means shall be provided to preset the cumulative on-time of the fluoroscopic x-ray tube. The maximum cumulative time of the timing device shall not exceed 5 minutes without resetting.
2. A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while x-rays are produced until the timing device is reset. As an alternative to the requirements of this subpart, radiation therapy simulation systems may be provided with a means to indicate the total cumulative exposure time during which x-rays were produced, and which is capable of being reset between examinations.
3. The total time of exposure shall be recorded.

6-005.08 Mobile Fluoroscopes: In addition to the other requirements of 180 NAC 6-005, mobile fluoroscopes shall provide intensified imaging.

6-005.09 Control of Scattered Radiation

1. Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall be not less than 0.25 millimeter lead equivalent.
2. Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless that individual:

    a. Is at least 120 centimeters from the center of the useful beam, or
    b. The radiation has passed through not less than 0.25 millimeter lead equivalent material including, but not limited to, (drapes, Bucky-slot cover panel, or self-supporting curtains) in addition to any lead equivalency provided by the protective apron referred to in 180 NAC 6-003.01, item 1.e.

3. The Agency may grant exceptions to 180 NAC 6-005.09, item 2., where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the Agency shall not permit such exception.

6-005.10 Radiation Therapy Simulation Systems: Radiation therapy simulation systems shall be exempt from all the requirements of 180 NAC 6-005.01, 6-005.03, 6-005.04, and 6-005.07 provided that:

1. Such systems are designed and used in such a manner that no individual other than the patient is in the x-ray room during periods of time when the system is producing x-rays; and
2. Systems which do not meet the requirements of 180 NAC 6-005.07 are provided with a means of indicating the cumulative time that an individual patient has been

exposed to x-rays. Procedures shall require in such cases that the timer be reset between examinations.

6-006 RADIOGRAPHIC SYSTEMS OTHER THAN FLUOROSCOPIC, DENTAL INTRAORAL, VETERINARIAN, OR COMPUTED TOMOGRAPHY X-RAY SYSTEMS:

6-006.01 Beam Limitation: The useful beam shall be limited to the area of clinical interest.

1. General Purpose Stationary and Mobile X-Ray Systems

   a. There shall be provided a means for stepless adjustment of the size of the x-ray field.
   b. A method shall be provided for visually defining the perimeter of the x-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed 2 percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.
   c. The Agency may grant an exemption on non-certified x-ray systems to 180 NAC 6-006.01, item 1.a. and b. provided the registrant makes a written application for such exemption and in that application:
      (1) Demonstrates it is impractical to comply with 180 NAC 6-006.01, item 1.a. and b.
      (2) The purpose of 180 NAC 6-006.01, item 1.a. and b. will be met by other methods.

2. Additional Requirements for Stationary General Purpose X-Ray Systems: In addition to the requirements of 180 NAC 6-006.01, item 1., all stationary general purpose x-ray systems shall meet the following requirements:

   a. A method shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within 2 percent of the SID, and to indicate the SID to within 2 percent;
   b. The beam-limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted; and
   c. Indication of field size dimensions and SID's shall be specified in inches and/or centimeters, and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within 2 percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.

3. X-Ray Systems Designed for One Image Receptor Size: Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID, or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

4. Systems Designed for or Provided with Special Attachments for Mammography: Radiographic systems designed only for mammography and general purpose radiographic systems, when special attachments for mammography are in service, shall be provided with means to limit the useful beam such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor at any designated SID except the edge of the image receptor designed to be adjacent to the chest wall where the x-ray field may not extend beyond this edge by more than 2 percent of the SID. This requirement can be met with a system which performs as prescribed in 180 NAC 6-006.01, item 5.c. When the beam-limiting device and image receptor support device are designed to be used to immobilize the breast during a mammographic procedure and the SID may vary, the SID indication specified in 180 NAC 6-006.01, item 5.c.(1). and (2). shall be the maximum SID for which the beam-limiting device or aperture is designed. In addition, each image receptor support intended for installation on a system designed only for mammography shall have clear and permanent markings to indicate the maximum image receptor size for which it is designed.

5. Special Purpose X-Ray Systems

   a. Means shall be provided to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2 percent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.
   b. Means shall be provided to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID, or means shall be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.
   c. 180 NAC 6-006.01, item 5.a. and b. may be met with a system that meets the requirements for a general purpose x-ray system as specified in 180 NAC 6-006.01, item 1. or, when alignment means are also provided, may be met with either:

      (1) An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or
      (2) A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

6-006.02 Radiation Exposure Control Devices

1. Timers: Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition, it shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.
2. X-Ray Control

a. An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time except for:

(1) Exposures of one-half (1/2) second or less, or
(2) During serial radiography when means shall be provided to permit completion of any single exposure of the series in process.

b. Each x-ray control shall be located in such a way as to meet the following requirements:

(1) Stationary x-ray systems shall be required to have the x-ray control permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure; and
(2) Mobile and portable x-ray systems which are:

(a) Used in one location, i.e., a room or suite, shall meet the requirements of subdivision 180 NAC 6-006.02, item 2.b.(1).
(b) Used in different locations shall provide operator protection at the controls by adequate shielding or operator positioning at a distance from the tube head of 12 feet (3.66m).

(3) The x-ray control shall provide visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

3. Automatic Exposure Controls: When an automatic exposure control is provided:

a. Indication shall be made on the control panel when this mode of operation is selected;
b. If the x-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to 2 pulses;
c. The minimum exposure time for all equipment other than that specified in 180 NAC 6-006.02, item 3.b. shall be equal to or less than one-sixtieth (1/60) second or a time interval required to deliver 5 mAs, whichever is greater;
d. Either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kWs per exposure or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except that, when the x-ray tube potential is less than 50 kVp, the product of x-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and
e. A visible signal shall indicate when an exposure has been terminated at the limits required by 180 NAC 6-006.02, item 3.d. and manual resetting shall be required before further automatically timed exposures can be made.

4. Reproducibility: With a timer setting of 0.5 seconds or less, the average exposure period (T) shall be greater than or equal to 5 times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when 4 timer tests are performed.

$$T \geq 5(T_{max} - T_{min})$$

6-006.03 Source-to-Skin Distance: All mobile or portable radiographic systems shall be provided with means to limit the source-to-skin distance to greater than or equal to 30 centimeters.

6-006.04 Exposure Reproducibility: The coefficient of variation of exposure shall not exceed 0.10 when all technique factors are held constant. This requirement shall be deemed to have been met if, when four exposures are made at identical technique factors, the value of the average exposure (E) is greater than or equal to 5 times the maximum exposure (E_{max}) minus the minimum exposure (E_{min}):

$$\bar{E} \geq 5(E_{max} - E_{min})$$

6-006.05 Radiation from Capacitor Energy Storage Equipment in Standby Status: Radiation emitted from the x-ray tube when the exposure switch or timer is not activated shall not exceed a rate of 2 milliroentgens (0.516 uC/kg) per hour at 5 centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.

6-006.06 Additional Requirements Applicable to Certified Systems Only. Diagnostic x-ray systems incorporating one or more certified component(s) shall be required to comply with the following additional requirement(s) which relate to that certified component(s).

1. Reproducibility: When the equipment is operated on an adequate power supply as specified by the manufacturer in accordance with the requirements of applicable Federal standards, the estimated coefficient of variation of radiation exposures shall be no greater than 0.05, for any specific combination of selected technique factors.
2. Linearity: When the equipment allows a choice of x-ray tube current settings and is operated on a power supply as specified by the manufacturer in accordance with the requirements of applicable Federal standards, for any fixed x-ray tube potential within the range of 40 to 100 percent of the maximum rating, the average ratios of exposure to the indicated milliampere-seconds product obtained at any 2 consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$| X_1 - X_2 | \leq 0.10 (X_1 + X_2)$$

where $\bar{X}_1$ and $\bar{X}_2$ are the average mR/mAs (uC/kg per mAs) values obtained at each of 2 consecutive tube current settings.

3. Accuracy: Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer.
4. Beam Limitation for Stationary and Mobile General Purpose X-Ray Systems:

    a. There shall be provided a means of stepless adjustment of the size of the x-ray field. The minimum field size at an SID of 100 centimeters shall be equal to or less than 5 centimeters by 5 centimeters.
    b. When a light localizer is used to define the x-ray field, it shall provide an average illumination of not less than 160 lux or 15 footcandles at 100

centimeters or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems are exempt from this requirement.

c. The edge of the light field at 100 centimeters or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than 4 in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than 3 in the case of beam-limiting devices designed for use on mobile equipment. The contrast ratio is defined as $1_1/1_2$ where 1_1 is the illumination 3 millimeters from the edge of the light field toward the center of the field; and 1_2 is the illumination 3 millimeters from the edge of the light field away from the center of the field. Compliance shall be determined with a measuring instrument aperture of 1 millimeter in diameter.

5. Beam Limitation for Portable X-Ray Systems: Beam limitation for portable x-ray systems shall meet the beam limitation requirements of 180 NAC 6-006.01, item 1. and 180 NAC 6-006.06, item 4.

6. Field Limitation and Alignment on Stationary General Purpose X-Ray Systems: The requirements of this subpart shall apply to stationary general purpose x-ray systems which contain a tube housing assembly, an x-ray control, and, for those systems so equipped, a table, all certified in accordance with 21 CFR 1020.30(c).

   a. Positive beam limitation (PBL) shall be provided whenever all the following conditions are met:
      (1) The image receptor is inserted into a permanently mounted cassette holder;
      (2) The image receptor length and width are each less than 50 centimeters;
      (3) The x-ray beam axis is within plus or minus 3 degrees of vertical and the SID is 90 centimeters to 130 centimeters inclusive; or the x-ray beam axis is within plus or minus 3 degrees of horizontal and the SID is 90 centimeters to 205 centimeters inclusive;
      (4) The x-ray beam axis is perpendicular to the plane of the image receptor to within plus or minus 3 degrees;
      (5) Neither tomographic nor stereographic radiography is being performed, and
      (6) The PBL system has not been intentionally overridden. This override provision is subject to 180 NAC 6-006.06, item 6.c.

   b. Positive beam limitation (PBL) shall prevent the production of x-rays when:

      (1) Either the length or width of the x-ray field in the plane of the image receptor differs, except as permitted by 180 NAC 6-006.06, item 6.e., from the corresponding image receptor dimensions by more than 3 percent of the SID; or
      (2) The sum of the length and width differences as stated in 180 NAC 6-006.06, item 6.b.(1), without regard to sign exceeds 4 percent of the SID.

c. If a means of overriding the positive beam limitation (PBL) system exists, that means:

(1) Shall be designed for use only in the event of PBL system failure or if the system is being serviced; and

(2) If in a position that the operator would consider it part of the operational controls or if it is referenced in the operator's manual or in other materials intended for the operator;

(a) Shall require that a key be utilized to defeat the PBL;

(b) Shall require that the key remain in place during the entire time the PBL system is overridden; and

(c) Shall require that the key or key switch be clearly and durably labeled as follows:
FOR X-RAY FIELD LIMITATION SYSTEM FAILURE

d. Compliance with 180 NAC 6-006.06, item 6.b. shall be determinedwhen the equipment indicates that the beam axis is perpendicular to the plane of the image receptor and the provisions of 180 NAC 6-006.06, item a. are met. Compliance shall be determined no sooner than 5 seconds after insertion of the image receptor.

e. The positive beam limitation system shall be capable of operation, at the discretion of the operator, such that the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. The minimum field size at an SID of 100 centimeters shall be equal to or less than 5 centimeters by 5 centimeters.

f. The positive beam limitation system shall be designed such that if a change in image receptor does not cause an automatic return to positive beam limitation function as described in 180 NAC 6-006.06, item 6.b. then any change of image receptor size or SID must cause the automatic return.

7. Timers: Except for dental panoramic systems, termination of exposure shall cause automatic resetting of the timer to its initial setting or to "zero."

a. Except during serial radiography, the operator shall be able to terminate the exposure at anytime during an exposure of greater than one-half second. Termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero. It shall not be possible to make an exposure when the timer is set to a zero or off position if either position is provided.

b. During serial radiography, the operator shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

8. Transmission Limit for Image Receptor Supporting Devices Used for Mammography: For x-ray systems manufactured after September 5, 1978 which are designed only for mammography, the transmission of the primary beam through any image receptor support provided with the system shall be limited such that the exposure 5 centimeters from any accessible surface beyond the plane of the image receptor supporting device does not exceed 0.1 milliroentgen (25.8 nC/kg) for each activation of the tube. Exposure shall be measured with the system operated at the minimum SID for which it is designed. Compliance shall be determined at the maximum rated peak tube potential for the system and at the maximum rated

product of tube current and exposure time (mAs) for that peak tube potential. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

6-007 INTRAORAL DENTAL RADIOGRAPHIC SYSTEMS: In addition to the provisions of 180 NAC 6-003 and 6-004, the requirements of 180 NAC 6-007 apply to x-ray equipment and associated facilities used for dental radiography. Requirements for extraoral dental radiographic systems are covered in 180 NAC 6-006.

6-007.01 Source-to-Skin Distance: X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit source-to-skin distance, to not less than:

1. 18 centimeters if operable above 50 kVp, or
2. 10 centimeters if not operable above 50 kVp.

6-007.02 Field Limitation

1. Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that:

   a. If the minimum SSD is 18 centimeters or more, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 7 centimeters; and
   b. If the minimum SSD is less than 18 centimeters, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 6 centimeters.

2. An open ended position indicating device shall meet the requirements of 180 NAC 6-004.03.

6-007.03 Timers: Means shall be provided to terminate the exposure at the preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition:

1. It shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.
2. Reproducibility. With a timer setting of 0.5 seconds or, not less than 0.1 second, the average exposure period ($\overline{T}$) shall be greater than or equal to 5 times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when 4 timer tests are performed;

$$\overline{T} \geq 5 (T_{max} - T_{min})$$

6-007.04 X-Ray Control

1. An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time, except for exposures of one-half (1/2) second or less.
2. Each x-ray control shall be located in such a way as to meet the following requirements:

a. Stationary x-ray systems installed after June 27, 1983 shall be required to have the x-ray control permanently mounted in a protected area, so that the operator is required to remain in the protected area during the entire exposure; and
b. Stationary x-ray systems installed prior to June 27, 1983, the operator shall remain in a protected area which permits compliance with 180 NAC 4-005 4-022, and 4-013 and
c. Mobile and portable x-ray systems which are:

(1) Used for greater than 1 week in the same location, i.e., a room or suite, shall meet the requirements of 180 NAC 6-007.04, item 2. a. and 6-007.04, item 2.b.; or
(2) Used for greater than 1 hour and less than 1 week at the same location, i.e., a room or suite, shall meet the requirements of 180 NAC 6-007.04, item 2.c.(1) or be provided with a 6.5 feet (1.98m) high protective barrier which is placed at least 6 feet (1.83m) from the tube housing assembly and at least 6 feet (1.83m) from the patient; or
(3) Used to make an exposure(s) of a patient at the use location shall meet the requirement of 180 NAC 6-007.04, item 2. c. (1) or (2) or be provided with a method of x-ray control which will permit the operator to be at least 12 feet (3.66m) from the tube housing assembly during an exposure.
(4) For those x-ray systems used infrequently to make an exposure(s) of a patient at the use location, it shall be provided with a method of x-ray control which will permit the operator to be at least 6 feet (1.83m) from the tube housing assembly or the patient and be out of the primary beam during the exposure.

3. The x-ray control shall provide visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

6-007.05 Exposure Reproducibility: The coefficient of variation shall not exceed 0.10 when all technique factors are held constant. This requirement shall be deemed to have been met if, when 4 exposures are made at identical technique factors, that the value of the average exposure (E) is greater than or equal to 5 times the maximum exposure (E_{max}) minus the minimum exposure (E_{max}):

$$\bar{E} \geq 5 (E_{max} - E_{min})$$

6-007.06 Administrative Controls

1. Patient and film holding devices shall be used when the techniques permit.
2. The tube housing and the position indicating device shall not be hand-held during an exposure.
3. For intraoral radiography, the x-ray system shall be operated in such a manner that the useful beam at the patient's skin does not exceed the requirements of 180 NAC 6-007.02, item 1.
4. Dental fluoroscopy without image intensification shall not be used.

6-007.07 Additional Requirements Applicable to Certified Systems Only: Only diagnostic x-ray systems incorporating one or more certified component(s) shall be required to comply with the following additional requirement(s) which relate to that certified component(s).

1. Reproducibility. When the equipment is operated on an adequate power supply as specified by the manufacturer, the estimated coefficient of variation of radiation exposures shall be no greater than 0.05, for any specific combination of selected technique factors.
2. Linearity. When the equipment allows a choice of x-ray tube current settings and is operated on a power supply as specified by the manufacturer in accordance with the requirements of applicable Federal standards, for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rating, the average ratios of exposure to the indicated milliampere-seconds product, obtained at any 2 consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$\left| \bar{X}_1 - \bar{X}_2 \right| \leq 0.10 \left(\bar{X}_1 + \bar{X}_2\right)$$

where $\bar{X}_1$ and $\bar{X}_2$ are the average mR/mAs values obtained at each of 2 consecutive tube current settings.
3. Accuracy. Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer.
4. Timers. Termination of exposure shall cause automatic resetting of the timer to its initial setting or to "zero."
5. Beam Quality. All certified dental xray systems manufactured on and after December 1, 1980, shall have a minimum half-value layer not less than 1.5 millimeters aluminum equivalent. Systems operating above 70 kVp are subject to the filtration requirements of 180 NAC 6-004.05, item 1.

6-008 THERAPEUTIC X-RAY SYSTEMS OF LESS THAN ONE MEV

6-008.01 Equipment Requirements

1. Leakage Radiation: When the tube is operated at its leakage technique factors, the leakage radiation shall not exceed the value specified at the distance specified for the classification of that x-ray system.

    a. Contact Therapy Systems. Leakage radiation shall not exceed 100 milliroentgens (25.8 uC/kg) per hour at 5 centimeters from the surface of the tube housing assembly.
    b. 0-l50 kVp Systems. Systems which were manufactured prior to June 27, 1983 shall have a leakage radiation which does not exceed 1 roentgen (0.258 mC/kg) in 1 hour at 1 meter from the source.
    c. 0-150 kVp Systems. Systems which are manufactured on or after June 27, 1983 shall have a leakage radiation which does not exceed 100 milliroentgens (25.8 uC/kg) in 1 hour at 1 meter from the source.
    d. 151 to 999 kVp Systems. The leakage radiation shall not exceed 1 roentgen (0.258 mC/kg) in 1 hour at 1 meter from the source except systems that operate in excess of 500 kVp may have a leakage radiation at 1 meter from the source not to exceed 0.1 percent of the useful beam one meter from the source.

2. Permanent Beam Limiting Devices: Permanent fixed diaphragms or cones used for limiting the useful beam shall provide the same or higher degree of protection as required by the tube housing assembly.
3. Removable and Adjustable Beam Limiting Devices

    a. Removable beam limiting devices shall, for the portion of the useful beam to be blocked by these devices, transmit not more than 1 percent of the useful beam at the maximum kilovoltage and maximum treatment filter. This requirement does not apply to auxiliary blocks or materials placed in the useful beam to shape the useful beam to the individual patient.
    b. Adjustable beam limiting devices installed after the effective date of Title 180 shall meet the requirements of 180 NAC 6-008.01, item 3.a.
    c. Adjustable beam limiting devices manufactured prior to August 1, 1974 and installed before the effective date of Title 180 shall, for the portion of the x-ray beam to be blocked by these devices, transmit not more than 5 percent of the useful beam at the maximum kilovoltage and maximum treatment filter.

4. Filter System: The filter system shall be so designed that:

    a. Filters cannot be accidently displaced at any possible tube orientation;
    b. Each filter is marked as to its material of construction and its thickness. For wedge filters, the wedge angle shall appear on the wedge or wedge tray; and
    c. The radiation at 5 centimeters from the filter insertion slot opening does not exceed 30 roentgens (7.74 mC/kg) per hour under any operating conditions.

5. Tube Immobilization: The tube housing assembly shall be capable of being immobilized for stationary treatments.
6. Focal Spot Marking: The tube housing assembly shall be so marked that it is possible to determine the location of the focal spot to within 5 millimeters, and such marking shall be readily accessible for use during calibration procedures.
7. Beam Block: Contact therapy tube housing assemblies shall have a removable shield of at least 0.5 millimeter lead equivalency at 100 kVp that can be positioned over the entire useful beam exit port during periods when the beam is not in use.
8. Reserved
9. Timer

    a. A timer shall be provided which has a display at the treatment control panel. The timer shall have a pre-set time selector and an elapsed time indicator.
    b. The timer shall be a cumulative timer which activates with the production of radiation and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator to zero.
    c. The timer shall terminate irradiation when a pre-selected time has elapsed if any dose monitoring system present has not previously terminated irradiation.
    d. The timer shall permit accurate presetting and determination of exposure times as short as 1 second.
    e. The timer shall not permit an exposure if set at zero.
    f. The timer shall not activate until the shutter is opened when irradiation is controlled by a shutter mechanism.

10. Control Panel Functions: The control panel, in addition to the displays required in other provisions of 180 NAC 6-008, shall have:

    a. An indication of whether electrical power is available at the control panel and if activation of the x-ray tube is possible;
    b. An indication of whether x-rays are being produced;
    c. Means for indicating x-ray tube potential and current;
    d. The means for terminating an exposure at any time;
    e. A locking device which will prevent unauthorized use of the x-ray system; and
    f. For x-ray equipment manufactured after June 27, 1983, shall have a positive display of specific filter(s) in the beam.

11. Multiple Tubes: When a control panel may energize more than one x-ray tube:

    a. It shall be possible to activate only one x-ray tube during any time interval;
    b. There shall be an indication at the control panel identifying which x-ray tube is energized; and
    c. There shall be an indication at the tube housing assembly when that tube is energized.

12. Source-to-Skin Distance: There shall be means of determining the source-to-skin distance to within 1 centimeter.
13. Shutters: Unless it is possible to bring the x-ray output to the prescribed exposure parameters within 5 seconds, the beam shall be automatically attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly. In addition,

    a. After the unit is at operating parameters, the shutter shall be controlled electrically by the operator from the control panel; and
    b. An indication of shutter position shall appear at the control panel.

14. Low-Filtration X-Ray Tubes: Each x-ray system equipped with a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and at the control panel.

6-008.02 Facility Design Requirements for X-Ray Systems Capable of Operating Above 50 kVp: In addition to shielding adequate to meet requirements of 180 NAC 4 and 180 NAC 6, the treatment room shall meet the following design requirements:

1. Aural Communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel; however, where excessive noise levels or treatment requirements make aural communication impractical, other methods of communication shall be used.
2. Viewing Systems.

    a. Windows, mirrors, closed-circuit television, or an equivalent system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.

b. When the primary viewing system is by electronic means an alternate viewing system, which may be electronic, shall be available for use in the event of failure of the primary viewing system.

3. Additional Requirements for X-Ray Systems Capable of Operation Above 150 kVp.

a. All protective barriers shall be fixed except for entrance doors or beam interceptors.
b. The control panel shall be located outside the treatment room.
c. Entrance Interlocks. Interlocks shall be provided such that all entrance doors must be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel.
d. When any door referred to in 180 NAC 6-008.02, item 3.c. is opened while the x-ray tube is activated, the exposure at a distance of 1 meter from the source shall be reduced to less than 100 milliroentgens (25.8 uC/kg) per hour.

6-008.03 Surveys, Calibrations, Spot Checks, and Operating Procedures

1. Surveys

a. All new facilities, and existing facilities not previously surveyed, shall have a survey made by, or under the direction of, a radiological physicist. In addition, such surveys shall also be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.
b. The registrant shall obtain a written report of the survey from the radiological physicist, and a copy of the report shall be transmitted by the registrant to the Agency within 30 days of receipt of the report.
c. The survey and report shall indicate all instances where the installation, in the opinion of the radiological physicist is in violation of applicable regulations.

2. Calibrations

a. The calibration of an x-ray system shall be performed at intervals not to exceed one year and after any change or replacement of components which could cause a change in the radiation output.
b. The calibration of the x-ray system shall be performed by a radiological physicist.
c. The calibration of radiation output of an x-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The system shall have been calibrated within the preceding 2 years.
d. The calibrations shall be such that the dose at a reference point in soft tissue can be calculated to an accuracy within ± 5 percent.
e. The calibration of the x-ray system shall include, but not be limited to, the following determinations:

(1) Verification that the x-ray system is operating in compliance with the design specifications;

(2) The exposure rates as a function of field size, technique factors, filter, and treatment distance used;
(3) The degree of congruence between the radiation field and the field indicated by the localizing device if such device is present; and
(4) An evaluation of the uniformity of the largest radiation field used.

f. Records of calibration shall be maintained by the registrant for 5 years after completion of the calibration.
g. A copy of the most recent x-ray system calibration shall be available at or in the area of the control panel.

3. Spot Checks: Spot checks shall be performed on x-ray systems capable of operation at greater than 150 kVp. Such spot checks shall meet the following requirements:

a. The spot-check procedures shall be in writing and shall have been developed by a radiological physicist. A copy of the procedures shall be available to the Agency.
b. If a radiological physicist does not perform the spot-check measurement, the results of the spot-check measurements shall be reviewed by a radiological physicist within 15 days.
c. The spot-check procedures shall specify the frequency at which tests or measurements are to be performed. The spot-check procedures shall specify that the spot check shall be performed during the calibration specified in 180 NAC 6-008.03, item 2. The acceptable tolerance for each parameter measured in the spot check when compared to the value for that parameter determined in the calibration specified in 180 NAC 6-008.03, item 2., shall be stated.
d. The cause for a parameter exceeding a tolerance set by the radiological physicist shall be investigated and corrected before the system is used for patient irradiation.
e. Whenever a spot check indicates a significant change in the operating characteristics of a system, as specified in the radiological physicist spot-check procedures, the system shall be recalibrated as required in 180 NAC 6-008.03, item 2.
f. Records of spot-check measurements shall be maintained by the registrant for 5 years after completion of the spot-check measurements and any necessary corrective actions.
g. Where a spot-check involves a radiation measurement, such measurement shall be obtained using a system satisfying the requirements of 006.08C2 or which has been intercompared with a system meeting those requirements within the previous year.

4. Operating Procedures

a. X-ray systems shall not be left unattended unless the system is secured against unauthorized use.
b. When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used.
c. The tube housing assembly shall not be held by hand during operation unless the system is designed to require such holding and the peak tube potential of

the system does not exceed 50 kVp. In such cases, the holder shall wear protective gloves and apron of not less than 0.5 mm lead equivalency at 100 kVp.

d. No individual other than the patient shall be in the treatment room unless such individual is protected by a barrier sufficient to meet the requirements of 180 NAC 4-006. No individual other than the patient shall be in the treatment room during exposures from x-ray systems operating above 150 kVp.

e. No person shall operate an accelerator until they meet the training requirements of 180 NAC 15-024.

f. The x-ray system shall not be used in the administration of radiation therapy unless the requirements of 180 NAC 6-008.03, item 2. and 180 NAC 6-008.03, item 3.e. have been met.

6-009 X-RAY AND ELECTRON THERAPY SYSTEMS WITH ENERGIES OF ONE MEV AND ABOVE: 180 NAC 9 except 180 NAC 9-011.03 and 180 NAC 9-011.04 shall apply to medical facilities using therapy systems with energies 1 MeV and above:

6-009.01 Definitions: In addition to the definitions provided in 180 NAC 6-002, the following definitions shall be applicable to 180 NAC 6-009:

1. "Applicator" means a structure which determines the extent of the treatment field at a given distance from the virtual source.
2. "Beam scattering filter" means a filter used in order to scatter a beam of electrons.
3. "Central axis of the beam" means a line passing through the virtual source and the center of the plane figure formed by the edge of the first beam limiting device.
4. "Dose monitoring system" means a system of devices for the detection, measurement, and display of quantities of radiation.
5. "Dose monitor unit" means a unit response from the dose monitoring system from which the absorbed dose can be calculated.
6. "Existing equipment" means therapy systems subject to 180 NAC 6-009 which were manufactured on or before January 1, 1985.
7. "Field flattening filter" means a filter used to provide dose uniformity over the area of a useful beam of x-rays at a specified depth.
8. "Field size" means the dimensions along the major axes of an area in a plane perpendicular to the specified direction of the beam of incident radiation at the normal treatment distance and defined by the intersection of the major axes and the 50 percent isodose line. Material shall be placed in the beam such that dose maximum is produced at the normal treatment distance when field size is being determined.
9. "Gantry" means that part of the system supporting and allowing possible movements of the radiation head.
10. "Interruption of irradiation" means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.
11. "Isocenter" means a fixed point in space located at the center of the smallest sphere through which the central axis of the beams passes in all conditions.
12. "Moving beam therapy" means radiation therapy with relative displacement of the useful beam and the patient during irradiation. It includes arc therapy, skip therapy, and rotational therapy.
13. "New equipment" means systems subject to 180 NAC 6-009 which were manufactured after January 1, 1985.
14. “Normal treatment distance" means:

(a) For electron irradiation, the virtual source to surface distance along the central axis of the useful beam as specified by the manufacturer for the applicator.

(b) For x-ray irradiation, the virtual source to isocenter distance along the central axis of the useful beam. For non-isocentric equipment, this distance shall be that specified by the manufacturer.

15. "Radiation head" means the structure from which the useful beam emerges.
16. "Shadow tray" means a device attached to the radiation head to support auxiliary beam limiting material.
17. "Stationary beam therapy" means radiation therapy without relative displacement of the useful beam and the patient during irradiation.
18. "Target" means that part of a radiation head source which by design intercepts a beam of accelerated particles with subsequent emission of other radiation.
19. "Virtual source" means a point from which radiation appears to originate.

6-009.02 Requirements for Equipment

1. Leakage Radiation to the Patient Area

a. New equipment shall meet the following requirements:

(1) For operating conditions, producing maximum leakage radiation, the absorbed dose in rads (grays) due to leakage radiation, including x-rays, electrons, and neutrons, at any point in a circular plane of 2 meters radius centered on and perpendicular to the central axis of the beam at the isocenter or normal treatment distance and outside the maximum useful beam size shall not exceed 0.1 percent of the maximum absorbed dose in rads (grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the plane surface. Measurements excluding those for neutrons shall be averaged over an area up to but not exceeding 100 square centimeters at the position specified. Measurements of the portion of the leakage radiation dose contributed by neutrons shall be averaged over an area up to but not exceeding 200 square centimeters.

(2) For each system, the registrant shall determine or obtain from the manufacturer the leakage radiation existing at the positions specified in 180 NAC 6-009.02, item 1.a.(1) for the specified operating conditions. Records on leakage radiation measurements shall be maintained for inspection by the Agency.

b. Existing equipment shall meet the following requirements:

(1) For operating conditions producing maximum leakage radiation, the absorbed dose in rads (grays) due to leakage radiation excluding neutrons at any point in a circular plane of 2 meter radius centered on a perpendicular to the central axis of the beam 1 meter from the virtual source, and outside the maximum size useful beam, shall not exceed 0.1 percent of the maximum absorbed dose in rads (grays) of the

unattenuated useful beam measured at the point of intersection of the central axis of the beam and the surface of the circular plane. Measurements shall be averaged over an area up to but not exceeding 100 square centimeters at the positions specified.

(2) For each system, the registrant shall determine or obtain from the manufacturer the leakage radiation existing at the positions specified in 180 NAC 6-009.02, item 1.b.(1) for the specified operating conditions. Records on radiation leakage shall be maintained for inspection by the Agency.

2. Leakage Radiation Outside the Patient Area for New Equipment

a. The absorbed dose in rads (grays) due to leakage radiation except in the area specified in 180 NAC 6-009.02, item 1.a.(1) when measured at any point l meter from the path of the charged particle, before the charged particle strikes the target or window, shall not exceed 0.1 percent for x-ray leakage nor 0.05 percent for neutron leakage of the maximum absorbed dose in rads (grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the circular plane specified in 180 NAC 6-009.02, item 1.a.(1).

b. The registrant shall determine, or obtain from the manufacturer, the actual leakage radiation existing at the positions specified in 180 NAC 6-009.02, item 2.a. for specified operating conditions. Radiation measurements excluding neutrons shall be averaged over an area up to but not exceeding 100 square centimeters. Neutron measurements shall be averaged over an area up to but not exceeding 200 square centimeters.

3. Beam Limiting Devices: Adjustable or interchangeable beam limiting devices shall be provided and such devices shall transmit no more than 2 percent of the useful beam at the normal treatment distance for the portion of the useful beam which is to be attenuated by the beam limiting device. The neutron component of the useful beam shall not be included in this requirement.

4. Filters

a. Each filter which is removable from the system shall be clearly marked with an identification number. Documentation available at the control panel shall contain a description of the filter. For wedge filters, the wedge angle shall appear on the wedge or wedge tray.

b. If the absorbed dose rate data required by 180 NAC 6-009.02, item 16., relates exclusively to operation with a field flattening or beam scattering filter in place, such filter shall be removable only by the use of tools.

c. For new equipment which utilizes a system of wedge filters, interchangeable field flattening filters, or interchangeable beam scattering filters:

(1) Irradiation shall not be possible until a selection of a filter has been made at the treatment control panel;

(2) An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position; and

(3) An interlock shall be provided to prevent irradiation if any filter selection operation carried out in the treatment room does not agree

with the filter selection operation carried out at the treatment control panel.

5. Beam Quality: The registrant shall determine, or obtain from the manufacturer, data sufficient to assure that the following beam quality requirements are met:

   a. The absorbed dose resulting from x-rays in a useful electron beam at a point on the central axis of the beam 10 centimeters greater than the practical range of the electrons shall not exceed the values stated in Table III. Linear interpolation shall be used for values not stated.

TABLE III

Maximum Energy of Electron Beam in MeV	X-Ray Absorbed Dose as a Fraction of Maximum Absorbed Dose
1	0.03
15	0.05
35	0.10
50	0.20

   b. Compliance with 180 NAC 6-009.02, item 5.a. shall be determine using:

      (1) A measurement within a phantom with the incident surface of the phantom at the normal treatment distance and normal to the central axis of the beam;
      (2) The largest field size available which does not exceed 15 by 15 centimeters; and
      (3) A phantom whose cross-sectional dimensions exceed the measurement radiation field by at least 5 centimeters and whose depth is sufficient to perform the required measurement.

   c. The absorbed dose at a surface located at the normal treatment distance, at the point of intersection of that surface with the central axis of the useful beam during x-ray irradiation, shall not exceed the limits stated in Table IV. Linear interpolation shall be used for values not stated.

TABLE IV

Maximum Photon Energy in MeV	Absorbed Dose at the Surface as a Fraction of the Maximum Absorbed Dose
1	0.80
2	0.70
5	0.60
15	0.50
35	0.40
50	0.20

d. Compliance with 180 NAC 6-009.02, item 5.c. shall be determined by measurements made:

(1) Within a phantom using an instrument which will allow extrapolation to the surface absorbed dose;
(2) Using a phantom whose size and placement meet the requirements of 180 NAC 6-009.02, item 5.b.;
(3) After removal of all beam modifying devices which can be removed without the use of tools, except for beam scattering or beam flattening filters; and
(4) Using the largest field size available which does not exceed 15 by 15 centimeters.

e. The registrant shall determine, or obtain from the manufacturer, the maximum percentage absorbed dose in the useful beam due to neutrons, excluding stray neutron radiation, for specified operating conditions.

6. Beam Monitors: All therapy systems shall be provided with radiation detectors in the radiation head.

a. New equipment shall be provided with at least two radiation detectors. The detectors shall be incorporated into two separate dose monitoring systems.
b. Existing equipment shall be provided with at least one radiation detector. This detector shall be incorporated into a primary dose monitoring system.
c. The detectors and the system into which that detector is incorporated shall meet the following requirements:

(1) Each dose monitoring system shall be capable of independently monitoring, interrupting, and terminating irradiation.
(2) Each detector shall form part of a dose monitoring system from whose readings in dose monitor units the absorbed dose at a reference point in the treatment volume can be calculated.

(3) Each detector shall be removable only with tools and shall be interlocked to prevent incorrect positioning.

(4) For new equipment, the design of the dose monitoring systems shall assure that:

(a) The malfunctioning of one system shall not affect the correct functioning of the second system; and

(b) The failure of any element common to both systems which could affect the correct function of both systems shall terminate irradiation.

(5) Each dose monitoring system shall have a legible display at the treatment control panel. For new equipment, each display shall:

(a) Maintain a reading until intentionally reset to zero;

(b) Have only one scale and no scale multiplying factors;

(c) Utilize a design such that increasing dose is displayed by increasing numbers and shall be so designed that, in the event of an overdoseage of radiation, the absorbed dose may be accurately determined; and

(d) In the event of power failure, the dose monitoring information required in 180 NAC 6-009.02, item 6.c.(5) displayed at the control panel at the time of failure shall be retrievable in at least one system for a 20-minute period of time.

7. Beam Symmetry: In new equipment inherently capable of producing useful beams with asymmetry exceeding 5 percent, the asymmetry of the radiation beam in two orthogonal directions shall be monitored before the beam passes through the beam limiting device. Facilities shall be provided so that, if the difference in dose rate between one region and another region symmetrically displaced from the central axis of the beam exceeds 5 percent of the central axis dose rate, indication of this condition is made at the control panel; and if this difference exceeds 10 percent, the irradiation is terminated.

8. Selection and Display of Dose Monitor Units

a. Irradiation shall not be possible until a selection of a number of dose monitor units has been made at the treatment control panel.

b. The pre-selected number of dose monitor units shall be displayed at the treatment control panel until reset manually for the next irradiation.

c. After termination of irradiation, it shall be necessary to reset the dosimeter display to zero before subsequent treatment can be initiated.

d. For new equipment after termination of irradiation, it shall be necessary to manually reset the pre-selected dose monitor units before irradiation can be initiated.

9. Termination of Irradiation by the Dose Monitoring System or Systems During Stationary Beam Therapy

a. Each primary system shall terminate irradiation when the pre-selected number of dose monitor units has been detected by the system.

b. If original design of the equipment included a second dose monitoring system, that system shall be capable of terminating irradiation when not more than 15 percent or 40 dose monitor units above the pre-selected number of dose monitor units set at the control panel has been detected by the second dose monitoring system.
c. For new equipment, a second dose monitoring system shall be present. The system shall be capable of terminating irradiation when not more than 10 percent or 25 dose monitoring units above the pre-selected number of dose monitor units set at the control panel has been detected by the second dose monitoring system.
d. For new equipment, an indicator on the control panel shall show which dose monitoring system has terminated irradiation.

10. Interruption Switches: It shall be possible to interrupt irradiation and equipment movements at any time from the operator's position at the treatment control panel. Following an interruption, it shall be possible to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a preselected value during an interruption, irradiation and equipment movements shall be automatically terminated.

11. Termination Switches: It shall be possible to terminate irradiation and equipment movements, or go from an interruption condition to termination conditions, at any time from the operator's position at the treatment control panel.

12. Timer

a. A timer which has a display shall be provided at the treatment control panel. The timer shall have a pre-set time selector and an elapsed time indicator.
b. The timer shall be a cumulative timer which activates with the production of radiation and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator to zero.
c. The timer shall terminate irradiation when a pre-selected time has elapsed if the dose monitoring systems have not previously terminated irradiation.
d. For new equipment after termination of irradiation and before irradiation can be reinitiated, it shall be necessary to manually reset the preset time selector.

13. Selection of Radiation Type: Equipment capable of both x-ray therapy and electron therapy shall meet the following additional requirements:

a. Irradiation shall not be possible until a selection of radiation type has been made at the treatment control panel.
b. An interlock system shall be provided to insure that the equipment can emit only the radiation type which has been selected.
c. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.
d. An interlock system shall be provided to prevent irradiation with x-rays except to obtain a port film when electron applicators are fitted.
e. An interlock system shall be provided to prevent irradiation with electrons when accessories specific for x-ray therapy are fitted.

f. The radiation type selected shall be displayed at the treatment control panel before and during irradiation.

14. Selection of Energy: Equipment capable of generating radiation beams of different energies shall meet the following requirements:

a. Irradiation shall not be possible until a selection of energy has been made at the treatment control panel.
b. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.
c. The nominal energy value selected shall be displayed at the treatment control panel before and during irradiation.
d. For new equipment, an interlock system shall be provided to terminate irradiation if the energy of the electrons striking the x-ray target or electron window deviates by more than 20 percent or 3 MeV, whichever is smaller, from the selected nominal energy.

15. Selection of Stationary Beam Therapy or Moving Beam Therapy: Equipment capable of both stationary beam therapy and moving beam therapy shall meet the following requirements:

a. Irradiation shall not be possible until a selection of stationary beam therapy or moving beam therapy has been made at the treatment control panel.
b. An interlock system shall be provided to insure that the equipment can operate only in the mode which has been selected.
c. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.
d. For new equipment, an interlock system shall be provided to terminate irradiation if:

(1) Movement of the gantry occurs during stationary beam therapy; or
(2) Movement of the gantry stops during moving beam therapy unless such stoppage is a preplanned function.

e. Moving beam therapy shall be so controlled to obtain the selected relationships between incremental dose monitor units and incremental angle of movement.

(1) For new equipment, an interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any 10 degrees of arc differs by more than 20 percent from the selected value.
(2) For new equipment, where gantry angle terminates the irradiation in arc therapy, the dose monitor units shall differ by less than 5 percent from the value calculated from the absorbed dose per unit angle relationship.

f. The mode of operation shall be displayed at the treatment control panel.
g. Where the dose monitor system terminates the irradiation in arc therapy, the termination of irradiation shall be as required by 180 NAC 6-009.02, item 9.

16. Absorbed Dose Rate Monitor: For new equipment, a system shall be provided from whose readings the absorbed dose rate at a reference point in the treatment volume can be calculated.[4] In addition:

    a. The dose monitor unit rate shall be displayed at the treatment control panel.
    b. If the equipment can deliver under any conditions an absorbed dose rate at the normal treatment distance more than twice the maximum value specified by the manufacturer for any machine parameters utilized, a device shall be provided which terminates irradiation when the absorbed dose rate exceeds a value twice the specified maximum. The value at which the irradiation will be terminated shall be in a record maintained by the registrant.

17. Location of Virtual Source and Beam Orientation: The registrant shall determine, or obtain from the manufacturer, the location with reference to an accessible point on the radiation head of:

    a. The x-ray target or the virtual source of x-rays; and
    b. The electron window or the virtual source of electrons if the system has electron beam capabilities.

6-009.03 Facility and Shielding Requirements: In addition to 180 NAC 4, the following design requirements shall apply:

1. Protective Barriers: All protective barriers shall be fixed except for entrance doors or beam interceptors.
2. Control Panel: The control panel shall be located outside the treatment room.
3. Viewing Systems

    a. Windows, mirrors, closed-circuit television, or an equivalent system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator may observe the patient from the control panel.
    b. When the primary viewing system is by electronic means, an alternate viewing system, which may be electronic, shall be available for use in the event of failure of the primary viewing system.

4. Aural Communications: Provision shall be made for two-way aural communication between the patient and the operator at the control panel. However, where excessive noise levels or treatment requirements makes aural communication impractical, other methods of communication shall be used.
5. Room Entrances: Treatment room entrances shall be provided with warning lights, in readily observable positions near the outside of all access doors to indicate when the useful beam is "on".
6. Entrance Interlocks: Interlocks shall be provided such that all entrance doors must be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to

[4]The radiation detectors specified in 6-009.02, item 6 may form part of this system.

operation without closing the door and reinitiating irradiation by manual action at the control panel.

6-009.04 Surveys, Calibrations, Spot Checks, and Operating Procedures

1. Surveys

a. All new facilities, and existing facilities not previously surveyed, shall have a survey made by, or under the direction of, a radiological physicist. In addition, such surveys shall also be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.
b. The registrant shall obtain a written report of the survey from the radiological physicist, and a copy of the report shall be transmitted by the registrant to the Agency within 30 days of receipt of the report.
c. The survey and report shall indicate all instances where the installation, in the opinion of the radiological physicist is in violation of applicable regulations.

2. Calibrations

a. The calibration of systems subject to 180 NAC 6-009 shall be performed in accordance with an established calibration protocol acceptable to the Agency[5] before the system is first used for irradiation of a patient and thereafter at time intervals which do not exceed 12 months and after any change which might significantly alter the calibration, spatial distribution, or other characteristics of the therapy beam.
b. The calibration shall be performed under the direct supervision of a radiological physicist who is physically present at the facility during the calibration.
c. Calibration radiation measurements required by 180 NAC 6-009.04, item 2. a. shall be performed using a dosimetry system:

(1) Having a calibration factor for cobalt-60 gamma rays traceable to a national standard;
(2) Which has been calibrated within the previous two years and after any servicing that may have affected its calibration;
(3) Which has been calibrated in such a fashion that an uncertainty can be stated for the radiation quantities monitored by the system; and
(4) Which has had constancy checks performed on the system as specified by a radiological physicist.

d. Calibrations shall be in sufficient detail that the dose at a reference point in soft tissue may be calculated to within an accuracy of $\pm$ 5 percent.
e. The calibration of the therapy beam shall include but not be limited to the following determinations:

[5]The calibration protocol published by the American Association of Physicists in Medicine is accepted as an established protocol. For other protocols, the user shall submit that protocol to the Agency for concurrence that the protocol is acceptable.

(1) Verification that the equipment is operating in compliance with the design specifications concerning the light localizer, side light, and back-pointer alignment with the isocenter when applicable, variation in the axis of rotation for the table, gantry, and jaw system, and beam flatness and symmetry at the specified depth.
(2) The absorbed dose rate at various depths of water for the range of field sizes used, for each effective energy, that will verify the accuracy of the dosimetry of all therapy procedures utilized with that therapy beam.
(3) The uniformity of the radiation field and any dependency upon the direction of the useful beam.
(4) Verification that existing depth-dose data and isodose charts applicable to the specific machine continue to be valid or are updated to existing machine conditions.
(5) Verification of transmission and electron buildup factors for all accessories such as wedges, shadow trays, and compensators.

f. Records of calibration measurements under 180 NAC 6-009.04, item 2. a. and dosimetry system calibrations under 180 NAC 6-009.04, item 2.c. shall be maintained for 5 years after completion of the full calibration.
g. A copy of the latest calibration performed pursuant to 180 NAC 6-009.04, item 2 a. shall be available in the area of the control panel.

3. Spot checks: Spot checks shall be performed on systems subject to 180 NAC 6-009 during calibrations and thereafter at intervals not to exceed one month. Such spot checks shall meet the following requirements.

a. The spot-check procedures shall be in writing and shall have been developed by a radiological physicist. A copy of the procedure shall be submitted to the Agency prior to its implementation.
b. If a radiological physicist does not perform the spot-check measurements, the results of the spot-check measurements shall be reviewed by a radiological physicist within 15 days.
c. The spot-check procedures shall specify the frequency at which tests or measurements are to be performed and the acceptable tolerance for each parameter measured in the spot check when compared to the value for that parameter determined in the calibration.
d. At intervals not to exceed one week, spot checks shall be made of absorbed dose measurements at a minimum of 2 depths in a phantom for photon beams.
e. Where a system has built-in devices which provide a measurement of any parameter during irradiation, such measurement shall not be utilized as a spot-check measurement.
f. The cause for a parameter exceeding a tolerance set by the radiological physicist shall be investigated and corrected before the system is used for patient irradiation.
g. Whenever a spot check indicates a significant change in the operating characteristics of a system, as specified in the radiological physicist's spot-check procedures, the system shall be recalibrated as required in 180 NAC 6-009.04, item 2.

h. Records of spot-check measurements shall be maintained by the registrant for a period of 5 years after completion of the spot-check measurements and any necessary corrective actions.

i. Where a spot-check involves a radiation measurement, such measurement shall be obtained using a system satisfying the requirements of 180 NAC 6-009.04, items 1. 2. and 3. or which has been intercompared with a system meeting those requirements within the previous year.

4. Operating Procedures:

a. No individual other than the patient shall be in the treatment room during treatment of a patient.

b. If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used.

c. No person shall operate an accelerator until they meet the training and experience requirements of 180 NAC 15-021.

d. The system shall not be used in the administration of radiation therapy unless the requirements of 180 NAC 6-009.04, item 1., 2. and 3. have been met.

6-010 VETERINARY MEDICINE RADIOGRAPHIC INSTALLATIONS

6-010.01 Equipment

1. The protective tube housing shall be equivalent to the requirements of 180 NAC 6-004.03.
2. Diaphragms or cones shall be provided for collimating the useful beam to the area of clinical interest and shall provide the same degree of protection as is required of the housing.
3. The total filtration permanently in the useful beam shall not be less than 0.5 millimeters aluminum equivalent for machines operating up to 50 kVp, 1.5 millimeters aluminum equivalent for machines operating between 50 and 70 kVp, and 2.5 millimeters aluminum equivalent for machines operating above 70 kVp.
4. A device shall be provided to terminate the exposure after a preset time or exposure.
5. A dead-man type of exposure switch shall be provided, together with an electrical cord of sufficient length, so that the operator can stand out of the useful beam and at least 6 feet (1.83m) from the animal during all x-ray exposures.

6-010.02 Structural Shielding: All wall, ceiling, and floor areas shall be equivalent to or provided with applicable protective barriers to assure compliance with 180 NAC 4-005, 4-011, and 4-013.

6-010.03 Operating Procedures

1. The operator shall be protected from the direct scatter radiation by a whole body protective barrier of 0.25 millimeter lead equivalent or shall be so positioned that the nearest portion of the body is at least 2 meters from the tube head and the nearest edge of the image receptor.
2. No individual other than the operator shall be in the x-ray room while exposures are being made unless such individual's assistance is required.

3. When an animal must be held in position during radiography, mechanical supporting or restraining devices should be used. If the animal must be held by an individual, that individual shall be protected with appropriate shielding devices, such as protective gloves and apron, and he shall be so positioned that no part of his body will be struck by the useful beam. The exposure of any individual used for this purpose shall be monitored.
4. Veterinary Assistant's Training Requirements. Effective November 15, 1990, veterinary assistant's shall have eight (8) hours of classroom instruction in the fundamentals of radiation safety, radiation detection instrumentation, radiographic equipment, state and federal regulations, operating and emergency procedures and case histories of radiography accidents as outlined in 180 NAC 15-024, "Minimum Training Requirements for Operators of Non-Human X-Ray" of Title 180.

6-011 COMPUTED TOMOGRAPHY SYSTEMS

6-011.01 Definitions: In addition to the definitions provided in 180 NAC 1-002 and 180 NAC 6-002, the following definitions shall be applicable to 180 NAC 6-011:

1. "Computed tomography dose index" means the integral from -7T to +7T of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan, that is:

$$\mathrm{CTDI} = \frac{1}{nT} \int_{-7T}^{+7T} D(z)\, dz$$

where:

z = Position along a line perpendicular to the tomographic plane.
D(z) = Dose at position z.
T = Nominal tomographic section thickness.
n = Number of tomograms produced in a single scan.

This definition assumes that the dose profile is centered around z=0 and that, for a multiple tomogram system, the scan increment between adjacent scans is nT.

2. "CTDI" (See "Computed tomography dose index").
3. "Contrast scale" means the change in the linear attenuation coefficient per CTN relative to water, that is:

$$\mathrm{CS} = \frac{u_x - u_w}{(\mathrm{CTN})_x - (\mathrm{CTN})_w}$$

where:

u_x = Linear attenuation coefficient of the material interest.
u_w = Linear attenuation coefficient of water. $(\mathrm{CTN})_x$ = CTN of the material of interest.
$(\mathrm{CTN})_w$ = CTN of water.

4. "CS" (See "Contrast scale").

5. "CT conditions of operation" means all selectable parameters governing the operation of a CT system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors as defined in 180 NAC 6-002.
6. "CT Gantry" means the tube housing assemblies, beam-limiting devices, detectors, and the supporting structures and frames which hold these components.
7. "CTN" (See "CT number").
8. "CT number" means the number used to represent the x-ray attenuation associated with each elemental area of the CT image.

$$CTN = \frac{k(u_x - u_w)}{u_w}$$

where:

k = A constant[6]
u_x= Linear attenuation coefficient of the material of interest.
u_w= Linear attenuation coefficient of water.

9. "Dose profile" means the dose as a function of position along a line.

10. "Elemental area" means the smallest area within a tomogram for which the x-ray attenuation properties of a body are depicted. (See also "Picture element").
11. "Multiple tomogram system" means a system which obtains x-ray transmission data simultaneously during a single scan to produce more than one tomogram.
12. "Noise" means the standard deviation of the fluctuations in CTN expressed as a percentage of the attenuation coefficient of water. Its estimate (s_n) is calculated using the following expression:

$$S_n = \frac{100 \times CS \times s}{u_w}$$

where:

CS = Contrast scale
u_w = Linear attenuation coefficient of water.
s = Estimated standard deviation of the CTN of picture elements in a specified area of the CT image.

13. "Nominal tomographic section thickness" means the full width at half-maximum of the sensitivity profile taken at the center of the cross-sectional volume over which x-ray transmission data are collected.
14. "Picture element" means an elemental area of a tomogram.
15. "Reference plane" means a plane which is displaced from and parallel to the tomographic plane.

[6]The constant has a normal value of 1,000 when the Houndsfield scale of CTN is used.

16. "Scan" means the complete process of collecting x-ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms.
17. "Scan increment" means the amount of relative displacement of the patient with respect to the CT system between successive scans measured along the direction of such displacement.
18. "Scan sequence" means a preselected set of two or more scans performed consecutively under preselected CT conditions of operation.
19. "Scan time" means the period of time between the beginning and end of x-ray transmission data accumulation for a single scan.
20. "Single tomogram system" means a CT system which obtains x-ray transmission data during a scan to produce a single tomogram.
21. "Tomographic plane" means that geometric plane which is identified as corresponding to the output tomogram.
22. "Tomographic section" means the volume of an object whose x-ray attenuation properties are imaged in a tomogram.

6-011.02 Requirements for Equipment

1. Termination of Exposure

   a. Means shall be provided to terminate the x-ray exposure automatically by either de-energizing the x-ray source or shuttering the x-ray beam in the event of equipment failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than 110 percent of its preset value through the use of either a backup timer or devices which monitor equipment function.
   b. A visible signal shall indicate when the x-ray exposure has been terminated through the means required by 180 NAC 6-011.02, item 1.a.
   c. The operator shall be able to terminate the x-ray exposure at any time during a scan, or series of scans under CT system control, of greater than one-half second duration.

2. Tomographic Plane Indication and Alignment

   a. For any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.
   b. For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane. This reference plane can be offset from the location of the tomographic planes.
   c. If a device using a light source is used to satisfy 180 NAC 6-011.02, item 2.a. or b., the light source shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux.

3. Beam-on and Shutter Status Indicators and Control Switches

   a. The CT x-ray control and gantry shall provide visual indication whenever x-rays are produced and, if applicable, whether the shutter is open or closed.
   b. Each emergency button or switch shall be clearly labeled as to its function.

4. Indication of CT Conditions of Operation: The CT System shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence shall be indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.
5. Entraneous Radiation: When data are being collected for image production, the radiation adjacent to the tube port shall not exceed that permitted by 180 NAC 6-004.03.
6. Maximum Surface CTDI Identification: The angular position where the maximum surface CTDI occurs shall be identified to allow for reproducible positioning of a CT dosimetry phantom.
7. Additional Requirements Applicable to CT X-Ray Systems Containing a Gantry Manufactured After September 3, 1985

    a. The total error in the indicated location of the tomographic plane or reference plane shall not exceed 5 millimeters.
    b. If the x-ray production period is less than one-half second, the indication of x-ray production shall be actuated for at least one-half second. Indicators at or near the gantry shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.
    c. The deviation of indicated scan increment versus actual increment shall not exceed plus or minus 1 millimeter with any mass of 0 to 100 kilograms resting on the support device. The patient support device shall be incremented from a typical starting position to the maximum incremented distance or 30 centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel.

    d. Premature termination of the x-ray exposure by the operator shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan.

6-011.03 Facility Design Requirements.

1. Aural Communication Provision shall be made for two-way aural communication between the patient and the operator at the control panel.
2. Viewing Systems

    a. Windows, mirrors, closed-circuit television, or an equivalent shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.
    b. When the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) shall be available for use in the event of failure of the primary viewing system.

6-011.04 Surveys, Calibrations, Spot Checks, and Operating Procedures

1. Surveys

a. All CT x-ray systems installed after the effective date of Title 180 and those systems not previously surveyed shall have a survey made by, or under the direction of, a radiological physicist. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.
b. The registrant shall obtain a written report of the survey from the radiological physicist, and a copy of the report shall be made available to the Agency upon request.

2. Radiation Calibrations

a. The calibration of the radiation output of the CT x-ray system shall be performed by, or under the direction of, a radiological physicist.
b. The calibration of a CT x-ray system shall be performed at intervals specified by a radiological physicist and after any change or replacement of components which, in the opinion of the radiological physicist could cause a change in the radiation output.
c. The calibration of the radiation output of a CT x-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The dosimetry system shall have been calibrated within the preceding two years.
d. CT dosimetry phantom(s) shall be used in determining the radiation output of a CT x-ray system. Such phantom(s) shall meet the following specifications and conditions of use:

(1) CT dosimetry phantom(s) shall be right circular cylinders of polymethyl methacrylate of density 1.19 plus or minus 0.01 grams per cubic centimeter. The phantom(s) shall be at least 14 centimeters in length and shall have diameters of 32.0 centimeters for testing CT x-ray systems designed to image any section of the body and 16.0 centimeters for systems designed to image the head or for whole body scanners operated in the head scanning mode.
(2) CT dosimetry phantom(s) shall provide means for the placement of a dosimeter(s) along the axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom. Means for the placement of dosimeters or alignment devices at other locations may be provided.
(3) Any effects on the doses measured due to the removal of phantom material to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom.
(4) All dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.

e. The calibration shall be required for each type of head, body, or whole-body scan performed at the facility.
f. Calibration shall meet the following requirements:

(1) The dose profile along the center axis of the CT dosimetry phantom for the minimum, maximum, and midrange values of the nominal tomographic section thickness used by the registrant shall be measurable. Where less than three nominal tomographic thicknesses can be selected, the dose profile determination shall be performed for each available nominal tomographic section thickness.

(2) The CTDI[7] along the two axes specified in 180 NAC 6-011.04, item 2.d.(2) shall be measured. The CT dosimetry phantom shall be oriented so that the measurement point 1.0 centimeter from the outer surface and within the phantom is in the same angular position within the gantry as the point of maximum surface CTDI identified. The CT conditions of operation shall correspond to typical values used by the registrant.

(3) The spot checks specified in 180 NAC 6-011.04, item 3. shall be made.

g. Calibration procedures shall be in writing. Records of calibrations performed shall be maintained for inspection by the Agency.

3. Spot Checks

a. The spot-check procedures shall be in writing and shall have been developed by a radiological physicist.

b. The spot-check procedures shall incorporate the use of a CT phantom which has a capability of providing an indication of contrast scale, noise, nominal tomographic section thickness, the resolution capability of the system for low and high contrast objects, and measuring the mean CTN for water or other reference material.

c. All spot checks shall be included in the calibration required by 180 NAC 6-011.04, item 2. and at time intervals and under system conditions specified by a radiological physicist.

d. Spot checks shall include acquisition of images obtained with the CT phantom(s) using the same processing mode and CT conditions of operation as are used to perform calibrations required by 180 NAC 6-011.04, item 2. The images shall be retained, until a new calibration is performed, in two forms as follows:

(1) Photographic copies of the images obtained from the image display device; and

(2) Images sorted in digital form on a storage medium compatible with the CT x-ray system.

e. Written records of the spot checks performed shall be maintained for inspection by the Agency.

4. Operating Procedures

[7]For the purpose of determining the CTDI, the manufacturer's statement as to the nominal tomographic section thickness for that particular system may be utilized.

a. The CT x-ray system shall not be operated except by an individual who has been specifically trained in its operation.

b. Information shall be available in the control area regarding the operation and calibration of the system. Such information shall include the following:

(1) Dates of the latest calibration and spot checks and the location within the facility where the results of those tests may be obtained.

(2) Instructions on the use of the CT dosimetry phantom(s) including a schedule of spot checks appropriate for the system, allowable variations for the indicated parameters, and the results of at least the most recent spot checks conducted on the system.

(3) The distance in millimeters between the tomographic plane and the reference plane if a reference plane is utilized; and

(4) A current technique chart available at the control panel which specifies for each routine examination the CT conditions of operation and the number of scans per examination.

c. If the calibration or spot check of the CT x-ray system identifies that a system operating parameter has exceeded a tolerance established by the radiological physicist, use of the CT x-ray system on patients shall be limited to those uses permitted by established written instructions of the radiological physicist.

APPENDIX 6-A
INFORMATION TO BE SUBMITTED BY PERSONS PROPOSING TO
CONDUCT HEALING ARTS SCREENING

Persons requesting that the Agency approve a healing arts screening program shall submit the following information and evaluation:

1. Name and adddress of the applicant and, where applicable, the names and addresses of agents within this state.

2. Diseases or conditions for which the x-ray examinations are to be used in diagnoses.

3. Description in detail of the x-ray examinations proposed in the screening program.

4. Description of the population to be examined in the screening program, i.e., age, sex, physical condition, and other appropriate information.

5. An evaluation of any known alternate methods not involving ionizing radiation which could achieve the goals of the screening program and why these methods are not used in preference to the x-ray examinations.

6. An evaluation by a qualified expert of the x-ray system(s) to be used in the screening program. The evaluation by the qualified expert shall show that such system(s) do satisfy all requirements of Title 180.

7. A description of the diagnostic film quality control program.

8. A copy of the technique chart for the x-ray examination procedures to be used.

9. The qualifications of each individual who will be operating the x-ray system(s).

10. The qualifications of each individual who will be supervising the operators of the x-ray system(s). The extent of supervision and the method of work performance evaluation shall be specified.

11. The name and address of the individual who will interpret the radiograph(s).

12. A description of the procedures to be used in advising the individuals screened and their private practitioners of the healing arts of the results of the screening procedure and any further medical needs indicated.

13. A description of the procedures for the retention or disposition of the radiographs and other records pertaining to the x-ray examinations.

APPENDIX 6-B

INFORMATION ON RADIATION SHIELDING REQUIRED FOR PLAN REVIEWS

In order for the Agency to provide an evaluation, technical advice, and official approval on shielding requirements for a radiation installation, the following information must be submitted.

1. The plans should show, as a minimum, the following:

   (a) The normal location of the x-ray system's radiation port; the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; the location of the operator's booth; and the location of the x-ray control panel.

   (b) The structural composition and thickness or lead equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

   (c) The dimensions of the room(s) concerned.

   (d) The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

   (e) The make and model of the x-ray equipment and the maximum technique factors.

   (f) The type of examination(s) or treatment(s) which will be performed with the equipment.

2. Information on the anticipated workload of the x-ray system(s).

3. If the services of a qualified expert have been utilized to determine the shielding requirements, a report, including all basic assumptions used, shall be submitted with the plans.

APPENDIX 6-C

DESIGN RECOMMENDATIONS FOR AN OPERATOR'S BOOTH

1. Space Requirements:

   (a) The operator shall be allotted not less than 7.5 square feet (0.697 m^2) of unobstructed floor space in the booth.

   (b) The operator's booth may be any geometric configuration with no dimension of less than 2 feet (0.61 m).

   (c) The space shall be allotted excluding any encumbrance by the x-ray control panel, such as overhang, cables, or other similar encroachments.

   (d) The booth shall be located or constructed such that unattenuated direct scatter radiation originating on the examination table or at the wall cassette not reach the operator's station in the booth.

2. Structural Requirements:

   (a) The booth walls shall be permanently fixed barriers of at least 7 feet (2.13 m) high.

   (b) When a door or movable panel is used as an integral part of the booth structure, it must have an interlock which will prevent an exposure when the door or panel is not closed.

   (c) Shielding shall be provided to meet the requirements of 180 NAC 4.

3. X-Ray Control Placement:

   The x-ray control for the system shall be fixed within the booth and:

   (a) Shall be at least 40 inches (1.02 m) from any open edge of the booth wall which is nearest to the examining table.

   (b) Shall allow the operator to use the majority of the available viewing windows.

4. Viewing System Requirements:

   (a) Each booth shall have at least one viewing device which will:

      (1) Be so placed that the operator can view the patient during any exposure, and

      (2) The device shall be so placed that the operator can have full view of any occupant of the room and should be so placed that the operator can view any entry into the room. If any door which allows access to the room can not be seen from the booth, then that door must have an interlock controlling the exposure which will prevent the exposure if the door is not closed.

   (b) When the viewing system is a window, the following requirements also apply:

(1) It shall have a viewing area of at least 1 square foot (0.0929m^2) with the lower edge of the window at least 4.5 feet (1.37m) above the floor.

(2) The distance between the nearest edge of the window and the open edge of the booth shall not be less than 18 inches (0.457m).

(3) The glass shall have the same lead equivalence as that required in the booth's wall in which it is mounted.

(c) When the viewing system is by mirrors, the mirror(s) shall be so located as to accomplish the general requirements of 180 NAC 6, Appendix 6-B, 4.(a).

(d) When the viewing system is by electronic means:

(1) The camera shall be so located as to accomplish the general requirements of 180 NAC 6, Appendix 6-C, 4.(a), and

(2) There shall be an alternate viewing system as a backup for the primary system.